HFL-55

U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

d15116

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas G. Miller
President
TGM Products, Inc.
88 Rome Street
Farmingdale, New York 11735

November 18, 1996

Ref.: 18-NYK-97

Dear Mr. Miller:

During an inspection of your firm located in Farmingdale , NY, on October 21 and 25, 1996 our investigators determined that your firm manufactures surgical instruments. Clip forceps, Stamey needles, hemoclips and other medical instruments manufactured by your firm are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that, the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain device history records to demonstrate that devices are manufactured in accordance with device master records.

2. Failure to perform planned and periodic audits in accordance with written procedures.

3. Failure to maintain adequate written procedures for device inspection and testing. The criteria for acceptance are not in writing.

4. The quality assurance program fails to include procedures as follows:
   a. a written schedule for the maintenance and cleaning of equipment.
   b. a procedure for handling and investigating complaints and failures of devices to meet any of their performance specifications.

Our inspection also determined that you have failed to update your device establishment registration. Federal regulations, 21 CFR 807.21, require that an establishment update its registration annually. We have included with this letter a registration form for your convenience.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to Laurence D. Daurio, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232.

Sincerely,

Lillian Aveta
Acting District Director